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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MARSHALL, GERSTEIN & BORUN LLP 6300 SEARS TOWER 233 S. WACKER DRIVE CHICAGO, IL 60606				
EXAMINER SIEW, JEFFREY				
ART UNIT		PAPER NUMBER		
1637				

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,301

Applicant(s)

DRMANAC, RADOJE

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-121 is/are pending in the application.
- 4a) Of the above claim(s) 102-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. This application contains claims 102-121 drawn to an invention nonelected with traverse in response filed 5/12/03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

2. The application references US serial numbers (see e.g. page 21 line 24). The current status of referenced applications should be updated.

3. Figure 1 is described in the Brief Description of the Drawings but the drawings actually contains Figures 1A to 1C.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-97,99 & 101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,401,267. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 47-97,99 & 101 are drawn to a method of identifying at least one nucleotide sequence comprising connecting nucleotide sequence of detected labeled probe with respective immobilized probe.

Claims 1-36 of US 6,401,267 are drawn to method of determining sequence by assembling the nucleic acid sequence from said overlapping sequences identified which represents a species of the genus claims 47-101 in that claims 1-36 are drawn to identification of stretch of nucleotides and genus claims include the scope that includes at least one nucleotide identified.

5. Claims 98 & 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,401,267 in further view of Duck et al (US4,876,187 Oct. 24, 1989).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 98 & 101 are drawn to a method of identifying at least one nucleotide sequence comprising connecting nucleotide sequence of detected labeled probe with respective immobilized probe with added limitation of RNAse or uracil glycosylase treatment.

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As described previously, claims 1-36 of US 6,401,267 are drawn to method of determining sequence by assembling the nucleic acid sequence from said overlapping sequences identified. Claims 37-40 are drawn to kit with sixmer probes.

Claims 1-40 are not drawn to RNase or uracil glycosylase.

Duck et al teach RNase and uracil glycosylase for washing unhybridized probes (see col. 9 lines 35-40 & col. 11 lines 16-45).

One of ordinary skill in the art would have been motivated to apply Duck et al's Rnase and uracil glycosylase treatment to method and kit claims 1-40 of US6,401,267 in order to remove unhybridized sequences. It would have been prima facie obvious to apply Duck et al's treatment to claims 1-40 in order to remove sequences in order to regenerate surfaces of support.

6. The response filed 10/03/03 regarding the double patenting rejections has been fully considered and deemed not persuasive. The response request that the double patenting rejection to be held in abeyance until an indication of allowance.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-55, 57, 59-75, 79-82, 84-91, 93-96, 101 rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al (4,988,617 Jan. 29, 1991).

Landegren et al teach a method of determining nucleotide sequence in which a target nucleic acid is contacted with a set of immobilized oligonucleotide probes and one labeled probe under a set of probes, covalently joining immobilized probe and labeled probe, detecting label and identifying sequence (see whole doc. esp.col. 11 line 46-col. 12 line 27). They teach using ligase (see col. 9 line 36). They teach using various different probes to detect various loci (see col.12 line 41-65). They teach using stringent washing (see col. 7 line 35-65). They also teach testing mRNA sequences (see col. 5 line 51-col. 6 line 17). They teach simultaneous and sequential steps in annealing and ligation (see col. 6 lines 52-60). They also teach using 9mer or 10mer size probes and target of 19 nucleotides or longer (see col. 8 lines 20-29). They teach using various probes such as fluorescein that permit multicolor analysis and radioisotopes (see col. 8 lines 47-68). The solid support may be nylon or dextran supports or agarose beads (see col. 11 line 60 & col. 12 line 25).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56,58,76-78, 97,99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al (4,988,617 Jan. 29, 1991 in view of Cantor (US5,503,980 April 2, 1996).

The teachings of Landegren are described previously (note especially the immobilization on various solid supports on col. 11 lines 58-col. 12 line 27).

Landegren et al explicitly do not teach sequencing chip, RNA probes or fragmentation.

Cantor teach sequencing chip (see col. 2 line 40). They also teach using RNA probes with uracil (see col. 5 lines 25-55). They teach fragmenting target nucleic acids with restriction enzymes (see col. 9 line 13-29).

One of ordinary skill in the art would have been motivated to apply Landegren et al's immobilized probes onto Cantor's sequencing chip in order to automate the detection of different targets. The use of a sequencing chip allows simultaneous and automated detection of different probes on an array. It would have been prima facie obvious to apply Landegren et al's detection method to Cantor's chip in order to simultaneously analyze multiple different targets.

Moreover, it would have been prima facie obvious to apply Cantor's teaching of RNA probes and fragmentation in order to sequence large pieces of nucleic acids and sequence RNA.

9. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al (4,988,617 Jan. 29, 1991 in view of Southern (WO89/10977 16 November 1989).

The teachings of Landegren are described previously (note especially the immobilization on various solid supports on col. 11 lines 58-col. 12 line 27).

Landegren do not teach glass supports.

Southern teach glass supports (see page 11 line 25).

One of ordinary skill in the art would have been motivated to apply Southern's glass supports to Landegren's probes in order to increase the number of bound probes. Southern

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teaches that the resolution of probes on glass supports is around 10 microns. It would have been prima facie obvious to apply Landegren's probes to Southern's glass support to increase the number of immobilized probes per area.

10. Claims 98 & 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al (4,988,617 Jan. 29, 1991 in view of Duck et al (US4,876,187 Oct. 24, 1989).

The teachings of Landegren et al are described previously.

Landegren et al do not teach RNase or uracil glycosylase.

Duck et al teach RNase and uracil glycosylase for washing unhybridized probes (see col. 9 lines 35-40 & col. 11 lines 16-45).

One of ordinary skill in the art would have been motivated to apply Duck et al's RNase and uracil glycosylase treatment to Landegren et al's method of detection in order to remove unhybridized sequences. It would have been prima facie obvious to apply Duck et al's treatment to Landegren et al's method in order to remove sequences in order to regenerate surfaces of support.

11. The response regarding the prior art rejections filed 10/03/03 has been fully considered and deemed not persuasive. The response states that Landegren et al do not teach sequencing by hybridization and do not teach step (d) involving compiling the sequence. First claims are examined based on their active steps, the introduction of the "sequencing by hybridization" is deemed insufficient in overcoming the prior art. The claim active steps still read on the prior art

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in that Landegren while determining base difference is still determining a sequence in the target. The term sequence would be inclusive of Landegren et al's mutation determination. Moreover, the response refers to step as a compiling step but the claim reads broadly on Landegren et al's determination of mutation with the labeled probe and immobilized probe. Moreover, the response states that Landegren method requires the test substance is separated from the probe. The claims do not recite a negative limitation. The claims read broadly on Landegren et al's method including their step of separation. The rejections are maintained.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "sequencing by hybridization" in claim 47 lies in the preamble and renders claims 47-101. It is unclear what the phrase imparts to the active steps.

SUMMARY

13. No claims allowed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the

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examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.


JEFFREY SIEW
PRIMARY EXAMINER

December 20, 2003